REMARKS

This Amendment is in response to the Office Action, dated August 11, 2004. In the foregoing amendments, claims 18, 23, 37, and 38 are cancelled, and claims 1, 3-6, 11, 14, 17, 19-22, 31, 32, and 39 are amended. Claims 25-29 currently stand allowed, and claims 2, 7-10, 30, 40-44, and 46 have been withdrawn but are still pending in the application. New claims 47-55 are added in the foregoing amendments. Presently, claims 1-6, 11-24, 31-39, and 45 stand rejected in the Office Action. Reconsideration of the Examiner's rejections in the Office Action in view of the foregoing amendments and following remarks is respectfully requested.

Allowable Subject Matter

Applicants acknowledge, with appreciation, the allowance of claims 25-29, and the indicated allowability of claims 19-23 if rewritten in independent form to include all of the limitations of the rejected base claim, independent claim 1, and any intervening claims.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

In the Office Action, claims 1, 3-7, 11-24, and 32 stand rejected for certain informalities recited by the Examiner in the Office Action. Applicants have attended to the informalities in the foregoing amendments and request reconsideration of the indefiniteness rejections.

With respect to the specifics of the Examiner's indefiniteness rejections, support for the use of the phrase "pressurizing chamber" in claim 1 may be found on page 13, line 16 of the present application which identifies that, in one embodiment, the phrase "pressurizing chamber" may encompass a syringe. In view of this discussion, Applicants believe that the phrase "pressurizing chamber" is not indefinite.

As to the indefiniteness rejection relating to the "chamber" recited in claim 2, the Examiner is directed to, for example, the discussion at page 16, line 29 to page 17, line 3 relating to handheld control device "500". This discussion identifies that the handheld control device may include a "chamber 520" which is illustrated in Figure 3. In view of the claim support in the specification and drawings, Applicants respectfully submit that the use of the word "chamber" in claims 2 is not indefinite. Claim 2 currently stands withdrawn. New claims 50 and 51 include this word and are believed to be encompass the invention of Group I set forth in the Examiner's July 9, 2004 Office Action, and are further readable on Species II (Figures 6A-6G) set forth in the same Office Action. Therefore, Applicants have addressed the Examiner's objection to the word "chamber" in this Amendment. Applicants previously elected to pursue the claims of Group I, Species II in this application.

With respect to the Examiner's indefiniteness rejection of claims 4 and 5, Applicants believe the foregoing amendments to these claims overcome the Examiner's indefiniteness rejections. Support for the "actuator(s)" set forth in claims 4 and 5 may be found, for example, at page 22, line 10 to page 23, line 2 of the present application wherein the "actuator(s)" may be a "plunger or stem control 1010", or "switches 1030a, 1030b", etc.

With respect to the Examiner's indefiniteness rejection of claim 11 relating to the first-third ports, the present application provides support for this language in Figures 6D and 6E and the accompanying discussion in the specification at page 20, lines 17-25, wherein the "second port" is identified with reference numeral "954" and the "third port" is identified with reference numeral "956". The "first port" is unnumbered in Figures 6D and 6E, but is readily inferable from these Figures as the text "FROM INJECTOR" is located immediately adjacent the unnumbered "port". Nonetheless, Applicants have included additional clarifying language in the

foregoing amendments to claim 11 to overcome the Examiner's indefiniteness rejection relating to the first-third ports. In view of the foregoing amendments and the support in the specification and drawings for the language used in claim 11, reconsideration of the Examiner's indefiniteness rejection of this claim is requested. Applicants have deleted the phrase "syringe pump" to attend to the Examiner's other objection to claim 11. Further, with respect to the Applicants' use of the phrase "low pressure fluid delivery system" in claim 11, full support for this language may found in the original specification at page 19, first full paragraph, and Figures 6A and 6B, wherein such a "low pressure fluid delivery system" may comprise "a source of saline 890 in fluid connection with a peristaltic pump 900 via an intervening drip chamber 910". Accordingly, Applicants respectfully submit that the phrase "low pressure fluid delivery system" is not indefinite and reconsideration of the Examiner's indefiniteness rejection is respectfully requested.

Finally, with respect to the Examiner's indefiniteness rejection of claim 32 relating to the use of the word "stopcock", Applicants have amended this claim to insert the phrase "multi-position valve" in place of the word "stopcock" to overcome this rejection. The Examiner is directed, for example, to the discussion at page 13, lines 23-27 of the specification relating to "valves 52 and 54", which are shown in Figure 1 of the drawings, for support for this change.

In view of the foregoing, Applicants respectfully request reconsideration of the Examiner's various indefiniteness rejections recited in the Office Action.

Claim Rejections Under 35 U.S.C. §102(b)

1. Claims 1, 3-6, and 11 stand rejected under 35 U.S.C. §102(b) for anticipation by U.S. Patent No. 5,002,528 to Palestrant. This rejection is respectfully traversed.

Claim 1, as amended, is directed to an injector system including a powered injector, a pressurizing chamber, a fluid path, and a manual control device. Additional clarifying language was added with respect to the manual control device, namely that this device is in operative connection with the injector and includes at least one actuator. The amended control device is further recited as comprising a preprogrammed injection mode wherein depression of the actuator causes the powered injector to deliver a preprogrammed injection of fluid. The language directed to the "preprogrammed injection mode" was previously generally set forth in claim 5, and was not specifically addressed by the Examiner in the Office Action.

The clarifying language added to claim 1 further defines over Palestrant. Palestrant discloses an entirely manual irrigation and drainage system that includes a syringe (22), an irrigation reservoir (12), and a drainage bag (42). A series of stopcocks (20, 32) is provided to selectively isolate the syringe (22), irrigation reservoir (12), and drainage bag (42). Palestrant in no way teaches or suggests a powered injector or manual control device associated with the injector and comprising an actuator, with the manual control device adapted to cause the powered injector to deliver a preprogrammed injection of fluid upon activation of the actuator, and is not relevant to amended claim 1.

In the patents cited in the Office Action, only Duchon discloses a powered injector apparatus and a hand held remote control (14) for controlling the injector. Applicants note that Duchon discloses that the hand-held control may provide a command signal to a console (12) of the injector so that the injector provides a continuously variable injection rate (See column 4, lines 61-67). However, Duchon in no way teaches or suggests a powered injector and manual control device therefor comprising an actuator, with the manual control device adapted to cause the powered injector to deliver a preprogrammed injection of fluid upon actuation of the actuator

as presently claimed. The teachings of Duchon are limited to a hand-held control that causes the injector to deliver a continuously variable injection of fluid (See, further, column 13, lines 6-13 of Duchon). In view of the foregoing, amended claim 1 is neither anticipated by nor would have been obvious over the teachings of Duchon.

Applicants further note that claim 19 is amended in the foregoing amendments to be in independent form and includes similar limitations to those found in amended claim 1, and distinguishes over Duchon for the same foregoing reasons. The Examiner previously indicated allowable subject matter in claim 19 and, in conjunction with the previously discussed clarifying language now present in claims 1 and 19, Applicants respectfully submit that claims 1 and 19 are in condition for allowance. Claim 2-6 and 20-22 are amended in the foregoing amendments to conform to the clarifying language added to claims 1 and 19 and to further define the invention.

Further, Applicants have added new claims 47-50 to depend from claim 1, and new claims 51-55 to depend from claim 19. These additional claims further define the claimed invention and are fully supported by the original disclosure.

2. Claim 11 stands rejected under 35 U.S.C. §102(b) for anticipation by Palestrant, as indicated previously. Claims 11 and 12 stand rejected under 35 U.S.C. §102(b) for anticipation by U.S. Patent No. 5,569,208 to Woelpper et al. ("Woelpper"). Claims 11, 14-18, and 24 stand rejected under 35 U.S.C. §102(b) for anticipation by U.S. Patent No. 6,221,045 to Duchon et al. Additionally, claims 11, 13, 31-33, 35-38, and 45 stand rejected under 35 U.S.C. §102(b) for anticipation by U.S. Patent No. 4,243,031 to Genese. These rejections are respectfully traversed.

Claim 11, as amended, includes clarifying language relating to the pressure isolation mechanism to further distinguish over the cited references. Specifically, amended claim 11 now

sets forth that the first and second ports (i.e., the "injector" and "patient" ports, respectively) are connected in both the first and second states of the valve. This configuration is shown in Figures 6D and 6E of the present application.

With respect to Palestrant and Woelpper, the Examiner cites, in each case, a conventional stopcock valve and, in particular, stopcock (20) in Palestrant and stopcock (64) in Woelpper. Applicants respectfully submit that such conventional stopcocks do not have a valve that is normally biased to one state and is then switchable to a second state when fluid pressure in one of the ports of the stopcock reaches a predetermined level. Such conventional stopcocks must be manually turned from one position to another position to allow fluid flow along a different path through the stopcock. Accordingly, claim 11 is not anticipated by the teachings of either Palestrant or Woelpper. The Examiner has failed to take into consideration the clear language in claim 11 stating that the pressure isolation mechanism includes a valve that is normally biased to a first state and is switchable to a second state under fluid pressure.

With respect to Genese, this patent discloses a shutoff device (10) for an I.V. administration device. The Examiner generally cited Figures 1, 3, and 4 of this patent in connection with claims 11 and 13. As may be seen in the cited Figures, the shutoff device (10) is adapted for use with a single source of fluid (i.e., solution container (12)). Genese does not teach or suggest an injection system for injecting an injection fluid into a patient, comprising a pressurizing device for supplying injection fluid under pressure and a secondary low pressure fluid delivery system as claimed in claim 11. Therefore, claim 11 is not anticipated by the teachings of Genese.

Moreover, while the shutoff device (10) in Figure 4 of Genese includes a lateral extension (145) in the form of a passage in housing (128), this lateral extension (145) is not

adapted for connection to a low pressure fluid delivery system as claimed in claim 11. The lateral extension (145) is associated with lateral tubing in the main fluid line (See column 3, lines 7-13) and, therefore, is associated with pump actuator (21). Accordingly, the shutoff device (10) disclosed by Genese has two "ports" associated with the pump actuator (21) and a single port associated with tubing ultimately connected to a patient via catheter. Thus, Genese does not teach or suggest in any way the pressure isolation mechanism set forth in claim 11, having a first port adapted for connection to a pressurizing device, a second port adapted for connection to a patient, and a third port adapted for connection to a low pressure fluid delivery system, nor can such an arrangement be derived from the teachings or Genese. For the foregoing reasons, claim 11 also distinguishes over Genese.

With respect to Duchon cited by the Examiner in connection with claim 11, this patent discloses a powered injector having a syringe holder (16) that encloses a syringe body (18). A manifold (26) is associated with the syringe body (18). The manifold (26), as shown in Figures 1A-1C, includes a syringe (i.e., "first") port (80), a patient (i.e., "second") port (84), and a saline (i.e., "third") port (82). A spool valve is disposed in the manifold and is spring-biased so that the patient port (84) is normally connected to the saline port (82). When pressure at syringe port (80) reaches a sufficient level, the biased spool valve is overcome so that the syringe port (80) is connected to the patient port (84) and the saline port (82) is disconnected from the patient port (84) (see, also, Figures 7A-7D of Duchon).

This is not the configuration claimed in claim 11. In claim 11, the first (i.e., injector) port is continuously connected to the third (i.e., patient) port. The first port is selectively connected to the third port (i.e., low pressure fluid delivery system port). In the arrangement disclosed by Duchon, the syringe port (80) is only in fluid connection with the patient port (84) when

sufficient pressure is present to overcome the biasing force applied to the spool valve. Applicants have included clarifying language to reflect the foregoing difference over Duchon. In particular, this clarifying language states that the first and second ports art connected in both the first and second states of the valve, which is clearly not the case in the Duchon arrangement. In view of the distinct difference between the port arrangement disclosed by Duchon and the claimed arrangement, Applicants submit that claim 11 also distinguishes over Duchon.

Claims 12-17, and 24 depend directly or indirectly from claim 11 and are also in condition for allowance for all the foregoing reasons.

3. Claims 31-33, 35-38, and 45 stand rejected under 35 U.S.C. §102(b) for anticipation by Genese. Additionally, claims 31-39 stand provisionally rejected for obviousness-type double patenting over claims 1, 3, 5, 11-15, and 18-22 of copending and commonly owned Application No. 10/237,139. In response to the provisional obviousness-type double patenting rejection, Applicants include herewith a Terminal Disclaimer to attend to this rejection.

Amended claim 31 includes analogous language to that added to claim 11 and discussed previously directed to the claimed orientation of the first-third ports. In claim 31, the first port is adapted for connection with the pump device via the multi-patient use section, the second port is adapted for connection with the patient, and the pressure isolation third port is adapted for connection to a source of medical fluid via the multi-patient use section. Accordingly, Applicant's previous comments concerning the Genese patent in connection with claim 11 are applicable to claim 31 and are incorporated herein by reference.

Moreover, claim 31 further sets forth that the first and second ports are connected by a lumen, as shown in Figures 6D and 6E of the present application. Since the first and second

ports are openly connected by a lumen, as illustrated in Figures 6D and 6E, the foregoing discussion relating to the connection between these two ports provided previously with respect to claim 11 and the Duchon patent is applicable to claim 31 and is incorporated herein by reference.

Furthermore, Applicants note that claim 31 requires a multi-patient use section and a per-patient use section having a pressure isolation mechanism. None of the patents cited by the Examiner teach or suggest a pressure isolation mechanism associated with a per-patient use section as presently claimed in claim 31. In Palestrant and Woelpper, the stopcocks cited by the Examiner are associated with the upstream/reusable portions of the disclosed devices, and are not associated with the downstream disposable portion of the devices (i.e. catheters). In both cases, the stopcocks are located upstream of a catheter connection for the disclosed devices, which would form the downstream disposable portion.

With respect to Duchon, it is apparent that manifold (26) is disposed in the syringe holder (16) and is, therefore, part of the multi-patient portion of the injection apparatus disclosed by Duchon.

With respect to Genese, the shutoff device (10) is located upstream of a catheter connection proximate to filter (23), (See Figure 1), and is therefore part of the upstream/reusable section of the overall I.V. administration device disclosed by Genese.

Accordingly, none of the patents cited by the Examiner teach or suggest a fluid path set having a multi-patient use section and a per-patient use section with a pressure isolation mechanism provided as part of the per-patient (i.e., disposable) section, and claim 31 distinguishes over the cited references for this additional reason.

Claims 32-36, 39, and 45 depend directly or indirectly form claim 31 and are also in condition for allowance for all the foregoing reasons.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the application is now in condition for allowance. Reconsideration of this application is respectfully requested.

Respectfully submitted,

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